K071725

As required by 21 CFR 807.92 (c) this 510(k) summary is prepared

Application Date:

11th May 2007

Applicant:

JUL 11 2007

Spectrum Medical Ltd.
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Official Correspondent:

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Proposed Device:

Blood Gas Monitor
Trade Name: M2 Monitor
Classification Name: Monitor, Blood-Gas, On-Line, Cardiopulmonary Bypass
21 CFR 870.4330, Product code: DRY

Predicate Devices:

K931968 3M Health Care Ltd, CDI 100 Extracorporeal Hematocrit / Oxygen Monitoring Device and K062468 Spectrum Medical Ltd, M2 Oxygen Saturation Monitor.

Description of Proposed Device:

The Spectrum M2 Monitor consists of a 10.4 inch high definition touch screen and three active measuring channels mounted into a flat panel unit. Sensor cables are used to connect the active measuring channels to the external surface of extracorporeal blood tubing. Two active measuring channels are used to measure venous and arterial oxygen saturation. The sensor cable head contains a light emitting diode that sends light through the extracorporeal tube, which illuminates the blood. The reflected spectra is collected by a fibre optic cable and quantified by a photo detector contained within a spectrometer. These spectra are compared to reference spectra by the monitor's software to determine the oxygen saturation of the

blood. The third active measuring channel is used to measure hematocrit or haemoglobin concentration. The sensor cable head contains a light emitting diode that transmits near-infra-red light through the extracorporeal tube. A photo diode measures a received light level. The level of signal attenuation is used to calculate hematocrit or haemoglobin concentration

Parameter values are displayed in both a digital and trended format. The M2 Monitor has been designed to self-detect the selected sensor and to automatically configure the required parameter display screens. The device can be configured by the trained clinician to set parameter specific alarms and to select either the display of hematocrit or haemoglobin concentration. Session data can be stored to a memory card supplied with the system or via a RS232 link to a remote computer.

The M2 Monitor is powered from the AC Mains supply and also incorporates a battery back-up that automatically switches on in the event of an interruption to the mains power supply. The system weighs 4.5 kg and is supplied with a pole mount clamp.

Intended Use of Proposed Device

The intended use of the M2 Monitor is for the non-invasive continuous monitoring of oxygen saturation and hematocrit / haemoglobin concentration of the blood in an extracorporeal circuit. The device provides monitoring information to trained clinicians and can be configured by them to set parameter specific alarms.

Summary of Technological Characteristics

The proposed device has the same technological characteristics as the predicate M2 monitor cleared under 510(k) K062468 with the exception of the measurement of hematocrit / haemoglobin concentration.

For the measurement of hematocrit / haemoglobin concentration the proposed device has the same technological characteristics as the CDI monitor cleared under 510(k) K931968. The major difference in the technological characteristics of the proposed device and the predicate CDI 100 device is that the proposed device provides a completely non-invasive measurement of the blood in the extracorporeal blood tubing while the predicate involves the use of a cuvette inserted into the blood tubing.

Substantial Equivalence Determination

The M2 Monitor has an intended use that is also featured in the predicate device. Performance data has been provided to show that the M2 Monitor can measure the oxygen saturation and hematocrit / haemoglobin concentration of blood and in extracorporeal circuit to an equivalent accuracy to its predicate device. The M2 Monitor is therefore considered substantially equivalent to its predicate device for the monitoring of oxygen saturation in extracorporeal blood line tubing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2007

Spectrum Medical Ltd.
c/o Mr. Jeff D. Rongero
Senior Project Engineer
12 Laboratory Dr.
Research Triangle, NC 27709

Re: K071725
M2 Monitor
Regulation Number: 21 CFR 870.4330
Regulation Name: Cardiopulmonary bypass on-line blood gas monitor
Regulatory Class: Class II (two)
Product Code: DRY
Dated: June 25, 2007
Received: June 25, 2007

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: M2 Monitor

Indications for Use:

The M2 Monitor is intended as a device for the non-invasive continuous monitoring of oxygen saturation, hematocrit and haemoglobin concentration of the blood in an extracorporeal circuit. The device provides monitoring information to trained clinicians and can be configured by them to set parameter specific alarm levels.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular
510(k) Number K071725